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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/675,393      | 09/30/2003  | Ruth Ann Corcoran    | CM2544MXL           | 6850             |

27752 7590 11/28/2005

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EXAMINER

GEMBEH, SHIRLEY V

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1614

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/675,393 | <b>Applicant(s)</b><br>CORCORAN ET AL. |  |
|                              | <b>Examiner</b><br>Shirley V. Gembeh | <b>Art Unit</b><br>1614                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/6/04</u> . | 6) <input type="checkbox"/> Other: ____  |



### **DETAILED ACTION**

Status of claims:

1. Claims 1-24 is pending.
2. Claims 1-24 is rejected.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on April 06, 2004 has been considered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

I. Claims 1- 2, 6, 7, 9, 17-18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte*

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*Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1- 2, 9 and 20 recites the broad recitation less than/greater than, and the claim also recites about which is the narrower statement of the range/limitation.

Also, in claims 6-7 and 17-18 recites the broad recitation about, and the claim also recites least, which is the narrower statement of the range/limitation.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

II. Claims 1, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Garlick, Jr. et al., US 5,695,746.

Garlick, Jr. et al., disclose the current claim 1, a liquid dentifrice (see abstract), having a viscosity of 500 PASCAL's (Pa.) at  $0.1 \text{ s}^{-1}$  at 25°C comprising:

- a. greater than about 2% by weight of surfactant (see col. 3 lines 50-52),
- b. greater than about 1.2% flavor (see col. 1 lines 58-60),
- c. greater than 50% liquid carrier materials comprising water and humectants in a ratio 0.65 :1.5 (see col. 2 lines 19-31).

With regards to claim 5: the dental abrasive is from about 2% to about 20% is recited at (see col. 3 lines 1-6). The water content in the instant claim 8 is recited at (see col. 2 lines 28-30).

### ***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

III. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garlick, Jr. et al., US 5,695,746 ('746) taken with Glandorf US 5,820,854, and Viltro et al., US 6,648,641.

Garlick, Jr. et al., teach the current claims 1 and 2, a liquid dentifrice (see abstract), having a viscosity of 500 Pascals (Pa.) at  $0.1 \text{ s}^{-1}$  at  $25^{\circ}\text{C}$  comprising:

- a. greater than about 2% by weight of surfactant (see col. 3 lines 50-52),
- b. greater than about 1.2% flavor (see col. 1 lines 58-60),
- c. greater than 50% liquid carrier materials comprising water and humectants in a ratio 0.65 : 1.5 (see col. 2 lines 19-31).

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With regards to claims 2, 5 and 16: the dental abrasive is from about 2% to about 20% is recited at (see col. 3 lines 1-6). The water content in the instant claims 8 and 19 is recited at (see col. 2 lines 28-30).

The '746 reference also teaches the current claims 6,7, 18 and 19, where the anionic surfactant is at least 0.5 % as in the current claims 6 and 18 and at least 2% in the current claims 7 and 19 is taught at (see col. 3 lines 50-52).

Glandorf is directed to a dentifrice formulation containing polyoxethylene (see col. 2 lines 10-15), having a molecular weight greater than 200,000, comprising 0.1 to 0.5% is taught at (see col. 2 lines 10-15) as in current claims 2-3 and 14.

Viltro et al., teach current claims 11,13 and 24, a brushing system- a dentifrice dispensing toothbrush, wherein the toothbrush dispenses a unit dose of the dentifrice taught at (see col. 2 lines 1-16), specifically in delivering a very precise efficacious amount (see col. 5 line 19-28) where the amount delivered would have been obvious to the skilled artisan in the art of dentistry to determine. Viltro et al., also teach a powered toothbrush (see col. 1 lines 57-60) as in current claims 12 and 23.

Although, the Viltro et al., reference did not teach the current claims 9 and 20, however, it would have been obvious to one of ordinary skill to make and use the claimed subject matter in a package having a cross-sectional area less than 10 mm<sup>2</sup> because the system maybe used to deliver a precise amount under a controlled system.

It would have been obvious matter of design to modify the Garlick, Jr. et al reference with that of Glandorf and Viltro et al., by adding the teachings of Glandorf and Viltro to that of Garlick, having the sonic toothbrush, integrated with a reservoir

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comprising a liquid dentifrice that dispenses a unit dose of the dentifrice, since applicant has not disclosed that having less than 1ml solves any problem or is for any particular purpose. It appears that having a unit disperse dose would perform equally well. Dosage dispensing is generally recognized as being within the level of ordinary skill in the art.

Therefore, one of ordinary skill in the art would have been motivated to combine the teachings of the above cited prior art, make and use the claimed subject matter at the time it was made, because of the above stated reasoning, and also because electric powered tooth brush is well known in the art (see col. 2 lines 4-16 of Viltro et al.). The invention is the combination of a liquid oral dentifrice and a powered electrical toothbrush with a reservoir.

Thus, the claimed subject matter was prima facie obvious to make and use at the time it was made.

**IV.** Claims 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garlick, Jr. et al., US 5,695,746 ('746) taken with Glandorf US 5,820,854, and Viltro et al., US 6,648,641.

In addition, the printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert of a kit and the product, composition, or article of manufacture of a kit or container.

See *In re Haller* 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of *In re Haller*, it is stated that: Whether the statement of intended use appears merely in the claim or in label on the product is immaterial so far as the question of Patentability is concerned. In accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Also see *In re Venezia* 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, *In re Miller* 164 USPQ 46 (CCPA 1969) and *In re Gulak* (CAFC) 217 USPQ 401 relate to a mathematical device and to a measuring cup respectively as well as *In re Ngai*, 70 USPQ2d 1862 (CAFC 2004). In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles or kits. The claimed articles of the kit remain fully functional absent the labeling or printed instructions for use.



Thus the instructions for use included in a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, the kit claims are drawn to an old article or composition, which further comprises labeling instructions. The intended use, which is recited on the label or package of the insert, lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, the old article or old composition of the kit can still be used by the skilled artisan for other purposes. Therefore the old article or composition which are comprised with the claimed kit are unpatentable over the prior art, because they function equally effectively with or without the labeling, and accordingly no functional relationship exists between the instructions for use and the composition.

Thus the claims are addressed as being drawn to an article of manufacture comprising an old composition of a kit and a package insert, the instructions on the

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insert bearing no patentable weight with regard to double patenting, 102 and 103 rejections.


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembah whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Kevin E. Weddington  
Primary Examiner  
Art Unit 1614